K110027

AUG - 5 2011

510(k) Summary

5.1 **Type of Submission:** Traditional

5.2 **Submitter:** Angeline Group Ltd.

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Phone: +886-2-8993-5668

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Contact: Charles Sun

Establishment Registration Number: N/A

5.3 **Identification of the Device:**

Proprietary/Trade name:	Surgical Face Mask, Type: Tie-on, Ear-loop
Common Name:	Surgical Face Mask, Disposable
Classification Name:	Mask, Surgical
Device Classification:	II
Regulation Number:	878.4040
Panel:	General & Plastic Surgery
Product Code:	FXX

5.4 **Identification of the Predicate Device:**

Predicate Device Name:	Non-Sterile Surgical Mask
Manufacturer:	A.R. Medicom Inc.
510(k) Number or Clearance Information:	K051291

5.5 **Intended Use and Indications for Use of the subject device.**

The Surgical Face Mask, Type: Tie-on, Ear-loop is indicated as a protective nose and mouth covering for health care workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism and body fluid.

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5.6 Device Description

Angeline Group Ltd. Surgical Face Mask, Type: Tie-on, Ear-loop are pleated 3-ply masks. The outer layers are made with 100% spun-bound polypropylene (SBPP). The filter media is composed of 10000 melt-blown polypropylene (MBPP). The inner layer is made of either 10000 medical grade tissue paper or 10000 SBPP. The ear loops are made of flat latex and fiberglass free elastic. The nosepieces are made of malleable aluminum wire. All of the materials used in the construction of the new masks are being used in currently marketed devices. The Surgical Face Mask, Type: Tie-on, Ear-loop is indicated as a protective nose and mouth covering for health care workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism, body fluid, and particulate aerosol transfer.

5.7 Non-clinical Testing

A series of in vitro and in vivo preclinical physical, mechanical and biocompatibility tests were performed to assess the safety and effectiveness of the Angeline Group Ltd. Surgical Face Mask. The physical and mechanical tests were conducted in accordance with EN 14683:2005 Surgical masks, Requirements and test methods, and the biocompatibility tests were conducted in accordance with ISO10993-5: 2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity. All the test results demonstrate the performance of Angeline Group Ltd. Surgical Face Mask meets the requirements of its pre-defined acceptance criteria and intended uses.

The results of the non-clinical testing demonstrate that the Angeline Group Ltd. Surgical Face Mask is as safe and effective as the predicate devices.

5.8 Safety and Effectiveness

The result of bench testing indicates that the new device is as safe and effective as the predicate device.

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5.9 Substantial Equivalence Determination

The Angeline Group Ltd. Surgical Face Mask submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared A.R. Medicom Inc. Non-Sterile Surgical Mask which is the subject of K051291. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Item	Predicate Device (K051291, A.R. Medicom Inc. Non-Sterile Surgical Mask)	Proposed Device (Angeline Group Ltd. Surgical Face Mask, Type: Tie-on, Ear-loop)
Similarity		
Intended Use	Intended as a protective nose and mouth covering for health care workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism, body fluid, and particulate aerosol transfer.	Same
Materials	Out layer: SBPP Filter: MBPP Inner Layer: SBPP Ear Loop: Elastic Nosepiece: Aluminum	Same Same Same Same Same
Sample types	Tie-on, Ear-loop	Same
Design	Fluid resistant Flat, pleated	Same Same
Sterile	No	Same
Single Use	Yes	Same
Difference		
Bacterial Filtration Efficiency	98%	99%

Performance (%)		
Fluid Resistance	ASTM F1862-05,	EN 14683: 2005,
Performance (mmHg)	Passed at 80 mmHg	Passed at 120 mmHg

5.10Conclusion

Angeline Group Ltd. Surgical Face Mask, Type: Tie-on, Ear-loop has the same intended use and technological characteristics as the predicate devices. Moreover, bench testing contained in this submission supplied demonstrates that the different technological characteristics do not raise any new questions of safety or effectiveness. In conclusion, Angeline Group Ltd. Surgical Face Mask, Type: Tie-on, Ear-loop maintains the same safety and effectiveness as the substantially equivalent predicate devices, Non-Sterile Surgical Mask.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Angeline Group Limited
C/O Mr. Michael Lee
President
ACME Biotechs Company, Limited
No.45, Minsheng Road
Danshui Town
Taipei County
China (Taiwan) 251

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Re: K110027
Trade/Device Name: Surgical Face Mask, Type: Tie-on, Ear-loop
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: July 20, 2011
Received: July 20, 2011

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110027

Device Name: Surgical Face Mask, Type: Tie-on, Ear-loop

Colors: White/Light Blue/Light Green/Light Yellow

Indications for Use:

The Surgical Face Mask, Type: Tie-on, Ear-loop is indicated as a protective nose and mouth covering for health care workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism and body fluid.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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